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PTO/SB/21 (09-04)

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

10

Application Number

10/732,897

Filing Date

December 9, 2003

First Named Inventor

Pennell, Andrew M.K.

Art Unit

1624

Examiner Name

Emily B. Bernhardt

Attorney Docket Number

019934-003720US

### ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement

- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
  - ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
  - ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) \_\_\_\_\_
  - ☐ Landscape Table on CD

- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):  
Form PTO/SB/08A&B (7 pp) and a Return Receipt Postcard

- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53

Remarks The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Townsend and Townsend and Crew LLP

Signature

Printed name

William B. Kezer

Date

7-11-06

Reg. No.

37,369

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TOWNSEND and TOWNSEND and CREW LLP

By



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Andrew M.K. Pennell et al.

Application No.: 10/732,897

Filed: December 9, 2003

For: SUBSTITUTED PIPERAZINES

Examiner: Emily B. Bernhardt

Art Unit: 1624

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants wish to make the Examiner aware of the following co-pending patent applications for the above-referenced instant application.

<u>USSN</u>	<u>Filed</u>	<u>Attorney Docket No.</u>
10/460,752	June 11, 2003	019934-003710US
10/979,882	November 1, 2004	019934-003730US
11/008,774	December 8, 2004	019934-003740US
11/071,880	March 2, 2005	019934-005010US

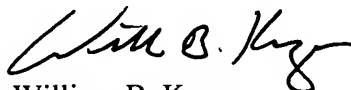
The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the

references cited can be found in Application No. 11/008,774, filed 12-08-2004 (Attorney Docket No. 019934-003740US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

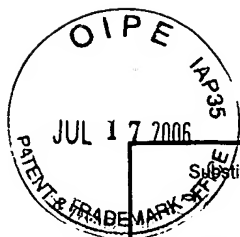
Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



William B. Kezer  
Reg. No. 37,369

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WBK:mrv  
60758769 v1



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/732,897
				Filing Date	December 9, 2003
				First Named Inventor	Pennell, Andrew M.K.
				Art Unit	1624
				Examiner Name	Emily B. Bernhardt
Sheet	1	of	7	Attorney Docket Number	019934-003720US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-3,362,956	01-09-1968	Archer	
	2	US-3,478,032	11-11-1969	Arya	
	3	US-3,491,098	01-20-1970	Archer	
	4	US-3,723,433	03-27-1973	Ueno et al.	
	5	US-3,950,354	04-13-1976	Wenselburger et al.	
	6	US-3,994,890	11-30-1976	Fujimura et al.	
	7	US-4,166,452	09-04-1979	Generales, Jr.	
	8	US-4,174,393	11-13-1979	Van Daalen et al.	
	9	US-4,256,108	03-17-1981	Theeuwes	
	10	US-4,265,874	05-05-1981	Bonsen et al.	
	11	US-4,310,429	01-12-1982	Lai	
	12	US-4,442,102	04-10-1984	Heinemann et al.	
	13	US-4,547,505	10-15-1985	Oepen et al.	
	14	US-4,559,341	12-17-1985	Petersen et al.	
	15	US-4,562,189	12-31-1985	Tomcufcik et al.	
	16	US-4,672,063	06-09-1987	Jasserand et al.	
	17	US-4,772,604	09-20-1988	Van Wijngaarden et al.	
	18	US-4,880,809	11-14-1989	Sugihara et al.	
	19	US-4,997,836	03-05-1991	Sugihara et al.	
	20	US-5,011,928	04-30-1991	Venero et al.	
	21	US-5,177,078	01-05-1993	Ward et al.	
	22	US-5,215,989	06-01-1993	Baldwin et al.	
	23	US-5,227,486	07-13-1993	Merce-Vidal et al.	
	24	US-5,292,739	03-08-1994	Merce Vidal et al.	
	25	US-5,346,896	09-13-1994	Ward et al.	
	26	US-5,382,586	01-17-1995	Merce Vidal et al.	
	27	US-5,464,788	11-07-1995	Bock et al.	
	28	US-5,580,985	12-03-1996	Lee et al.	
	29	US-5,607,936	03-04-1997	Chiang et al.	
	30	US-5,646,151	07-08-1997	Kruse et al.	
	31	US-5,681,954	10-28-1997	Yamamoto et al.	
	32	US-5,719,156	02-17-1998	Shue et al.	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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	33	US-5,756,504	05-26-1998	Bock et al.	
	34	US-5,760,028	06-02-1998	Jadhav et al.	
	35	US-5,760,225	06-02-1998	Yuan	
	36	US-5,780,475	07-14-1998	Baker et al.	
	37	US-5,798,359	08-25-1998	Shue et al.	
	38	US-5,968,938	10-19-1999	Williams et al.	
	39	US-6,114,334	09-05-2000	Kerrigan et al.	
	40	US-6,191,159	02-20-2001	Pinto	
	41	US-6,207,665 B1	03-27-2001	Bauman et al.	
	42	US-6,288,083 B1	09-11-2001	Luly et al.	
	43	US-6,329,385 B1	12-11-2001	Luly et al.	
	44	US-2002-0022624 A1	02-21-2002	Dinnell et al.	
	45	US-2002-0040020	04-04-2002	Bretenbucher et al.	
	46	US-2002-0045613 A1	04-18-2002	Pauls et al.	
	47	US-2002-0045749	04-18-2002	Lai	
	48	US-2002-0049205	04-25-2002	Li et al.	
	49	US-6,384,035 B1	05-07-2002	Hutchings et al.	
	50	US-2002-0077321	06-20-2002	Khanna et al.	
	51	US-2002-0107255	08-08-2002	Blumberg et al.	
	52	US-2002-0119961 A1	08-29-2002	Blumberg et al.	
	53	US-6,451,399	09-17-2002	Patel	
	54	US-6,455,544 B1	09-24-2002	Friedhoff et al.	
	55	US-6,469,041	10-22-2002	Yuan	
	56	US-6,492,375	12-10-2002	Snutch	
	57	US-6,518,273 B1	02-11-2003	Chapman et al.	
	58	US-2003-0087917 A1	05-08-2003	Starck et al.	
	59	US-2003-0139425 A1	07-24-2003	Bauman et al.	
	60	US-2003-0149021 A1	08-07-2003	Li et al.	
	61	US-2004-0162282-A1	08-19-2004	Andrew M.K. Pennell et al.	
	62	US-2005-025130-A1	11-17-2005	Andrew M.K. Pennell et al.	

### FOREIGN PATENT DOCUMENTS

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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	63	EP	0 479 546	A2	04-08-1992	John Wyeth & Brother		<input type="checkbox"/>
	64	EP	1 006 110	A1	06-07-2000	Laboratorios Del Dr. Esteve, S.A.		<input type="checkbox"/>
	65	WO	97/10219	A1	03-20-1997	Fujisawa Pharmaceutical Co., Ltd.		<input type="checkbox"/>
	66	WO	97/44329	A1	11-27-1997	Teijin Limited		<input type="checkbox"/>
	67	WO	98/25617	A1	06-18-1998	Merck & Co.		<input type="checkbox"/>
	68	WO	98/39000	A1	09-11-1998	Eisai Co., Ltd.		<input type="checkbox"/>
	69	WO	98/56771	A2	12-17-1998	Schering Aktiengesellschaft		<input type="checkbox"/>
	70	WO	99/07351	A2	02-18-1999	ZENECA LIMITED		<input type="checkbox"/>
	71	WO	99/09984	A1	03-04-1999	MERCK & CO., INC.		<input type="checkbox"/>
	72	WO	99/25686	A1	05-27-1999	COMBICHEM, INC.		Abstract
	73	WO	99/32468	A1	07-01-1999	TAKEDA CHEMICAL INDUSTRIES, LTD.		Abstract
	74	WO	99/37619	A1	07-29-1999	Leukosite, Inc.		<input type="checkbox"/>
	75	WO	99/37651	A1	07-29-1999	Leukosite, Inc.		<input type="checkbox"/>
	76	WO	00/31032	A1	06-02-2000	F. HOFFMANN-LA ROCHE AG		Abstract
	77	WO	00/46195	A1	08-10-2000	ASTRAZENECA AB		<input type="checkbox"/>
	78	WO	00/46196	A1	08-10-2000	ASTRAZENECA AB		<input type="checkbox"/>
	79	WO	00/46197	A1	08-10-2000	ASTRAZENECA AB		<input type="checkbox"/>
	80	WO	00/46198	A1	08-10-2000	ASTRAZENECA AB		
	81	WO	00/46199	A1	08-10-2000	ASTRAZENECA AB		
	82	WO	00/47539	A1	08-17-2000	Mitsui Chemicals, Inc.		
	83	WO	00/53600	A1	09-14-2000	Banyu Pharmaceutical Co.		
	84	WO	00/69815	A1	11-23-2000	TEIJIN LIMITED		
	85	WO	00/69820	A1	11-23-2000	COMBICHEM, INC.		
	86	WO	00/69848	A1	11-23-2000	MERCK & CO., INC.		
	87	WO	02/008221	A3	01-31-2002	Neurogen Corp.		
	88	WO	02/14314	A2	02-21-2002	Ortho Mcneil Pharmaceutical, Inc.		
	89	WO	02/070523	A1	09-12-2002	Pfizer Products Inc.		

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		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	90	WO	03/008395	A1	01-30-2003	Laboratorios S.A.L.V.A.T., S.A.		
	91	WO	03/024450	A1	03-27-2003	Eisai Co. Ltd.		
	92	WO	03/0051842	A2	06-26-2003	Novo Nordisk A/S		
	93	WO	04/009550	A1	01-29-2004	Pfizer Products Inc.		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	94	ANDERS, et al., A chemokine receptor CCR-1 antagonist reduces renal fibrosis after unilateral ureter ligation. J Clin Invest. (2002) 109(2):251-9.	<input type="checkbox"/>	
	95	BADRAN, M. et al., "Indazole derivatives (part III): synthesis of pyrazolo-[1,2-a]indazole-1,9-dione,[1,2,4]triazino[1,2-a]indazole-1,10-dione, 3-(Indazol-1-yl)propionic acid amides and hydrazides possessing potential biological activity" Alex. J. Pharm. Sci. (1999) 13(2):101-106.	<input type="checkbox"/>	
	96	BENDELE, et al., Animal models of arthritis: relevance to human disease, Toxicologic Pathol. (1999) 27:134-142	<input type="checkbox"/>	
	97	BERGE, S.M., et al., Pharmaceutical Salts, Journal of Pharmaceutical Sciences (1977) 66:1-19	<input type="checkbox"/>	
	98	CZARNOCKA-JANOWICZ, A. et al., "Synthesis and pharmacological activity of 5-substituted-s-triazole-3-thiols" Pharmazie (1991) 46:109-112.	<input type="checkbox"/>	
	99	DATABASE CROSSFIRE BEILSTEIN 'Online! Beilstein Institut zur Forderung der Chemischen Wissenschaften, Frankfurt am Main, DE; Database accession no. BRN 6982047 XP002254060 abstract & VARASI et al., Farmaco Ed. Sci. (1987) 42(6):425-436.	<input type="checkbox"/>	
	100	DATABASE CROSSFIRE BEILSTEIN 'Online! Beilstein Institut zur Forderung der Chemischen Wissenschaften, Frankfurt am Main, DE; Database accession no. BRN 1159762 XP002254062 abstract & ZOTTA et al. FARMACIA (1977) 25:129-134.	<input type="checkbox"/>	

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	101	DATABASE CROSSFIRE BEILSTEIN 'Online! Beilstein Institut zur Forderung der Chemischen Wissenschaften, Frankfurt am Main, DE; Database accession no. BRN 6000843 XP002254061 abstract & TOJA et al., <i>Heterocycles</i> (1987) 26(8):2129-2138.	<input type="checkbox"/>	
	102	DEVRIES, M. et al., "On the edge: the physiological and pathophysiological role of chemokines during inflammatory and immunological responses" <i>Sem. Immun.</i> (1999) 11:95-104.	<input type="checkbox"/>	
	103	FISCHER, F. et al., "Modulation of experimental autoimmune encephalomyelitis: effect of altered peptide ligand on chemokine and chemokine receptor expression" <i>J. Neuroimmun.</i> (2000) 110:195-208.	<input type="checkbox"/>	
	104	FOKS, H. et al., "Synthesis of new 5-substituted 1,2,4-triazole-3-thione derivatives" <i>Phosphorus, Sulfur and Silicon</i> (2000) 164:67-81.	<input type="checkbox"/>	
	105	GAO, et al., Targeting of the chemokine receptor CCR1 suppresses development of acute and chronic cardiac allograft rejection, <i>J Clin Invest.</i> (2000) 105(1):35-44.	<input type="checkbox"/>	
	106	HAYAO, S. et al., "New antihypertensive aminoalkyltetrazoles" <i>J. Med. Chem.</i> (1967) 10:400-402.	<input type="checkbox"/>	
	107	HCAPLUS; Accession No. 1984:630511, Document No. 101:230511; Japanese Patent No. 59130890, issued 07/27/1984; ABSTRACT, 4 pages.	<input type="checkbox"/>	
	108	HESSELGESSER, J. et al., "Identification and characterization of small molecule functional antagonists of the CCR1 chemokine receptor" <i>J. Biol. Chem.</i> (1998) 273(25):15687-15692.	<input type="checkbox"/>	
	109	IZIKSON, L. et al., "Resistance to experimental autoimmune encephalomyelitis in mice lacking the CC chemokine receptor (CCR2)" <i>J. Exp. Med.</i> (2000) 192(7):1075-1080.	<input type="checkbox"/>	
	110	KENNEDY, K. et al., "Role of chemokines in the regulation of Th1/Th2 and autoimmune encephalomyelitis" <i>J. Clin. Immunol.</i> (1999) 19(5):273-279.	<input type="checkbox"/>	
	111	LIANG, M. et al., "Species selectivity of a small molecule antagonist for the CCR1 chemokine receptor" <i>Eur. J. Pharmacol.</i> (2000) 389:41-49.	<input type="checkbox"/>	
	112	LIANG, M. et al., "Identification and characterization of a potent, selective, and orally active antagonist of the CC chemokine receptor" <i>J. Biol. Chem.</i> (2000) 275(25):19000-19008.	<input type="checkbox"/>	
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	113	MONTECLARO, et al., The amino-terminal domain of CCR2 is both necessary and sufficient for high affinity binding of monocyte chemoattractant protein 1. Receptor activation by a pseudo-tethered ligand, <i>J Biol Chem.</i> (1997) 272(37):23186-90.	<input type="checkbox"/>	
	114	NG, H. et al., "Discovery of novel non-peptide CCR1 receptor antagonists" <i>J. Med. Chem.</i> (1999) 42:4680-4694.	<input type="checkbox"/>	
	115	NICOLAI, E. et al., "Synthesis and angiotensin II receptor antagonist activity of C-linked pyrazole derivatives" <i>Chem. Pharm. Bull.</i> (1994) 42(8):1617-1630.	<input type="checkbox"/>	
	116	PATENT ABSTRACTS OF JAPAN, vol. 007, no. 139 (C-171), 17 June 1983 (1983-06-17) & JP 58 052256 A (Nippon Noyaku KK), 28 March 1983 abstract.	<input type="checkbox"/>	
	117	PLATER-ZYBERK, C. et al., "Effect of a CC chemokine receptor antagonist on collagen induced arthritis in DBA/1 mice" <i>Ummun. Lett.</i> (1997) 57:117-120.	<input type="checkbox"/>	
	118	PODOLIN, et al., A potent and selective nonpeptide antagonist of CXCR2 inhibits acute and chronic models of arthritis in the rabbit, <i>J. Immunol.</i> (2002) 169(11):6435-6444	<input type="checkbox"/>	
	119	ROSSI, D., et al., The biology of chemokines and their receptors, <i>Annu Rev Immunol.</i> (2000) 18:217-42.	<input type="checkbox"/>	
	120	ROTTMAN, J. et al., "Leukocyte recruitment during onset of experimental allergic encephalomyelitis is CCR1 dependent" <i>Eur. J. Immunol.</i> (2000) 30:2372-2377.	<input type="checkbox"/>	
	121	SAEKI, T., et al., CCR1 chemokine receptor antagonist, <i>Curr Pharm Des.</i> (2003) 9:1201-1208	<input type="checkbox"/>	
	122	SciFinder Report; Piperazine, 1-[(4-nitro-1H-imidazol-1-yl)acetyl]-4-phenyl-(9CI); Registry No.: 312707-74-7; Catalogs: STN Chemcats, Exploratory Library, Interchim Intermediates, AsinEx Express Gold Collection, and Pharma Library Collection; report dated 30 September 2003; 7 pages.	<input type="checkbox"/>	
	123	SciFinder Report; Piperazine, 1-[(3,5-dimethyl-4-nitro-1H-pyrazol-1-yl)acetyl]-4-(4-fluorophenyl)-(9CI); Registry No.: 356039-23-1; Catalogs: STN Chemcats, Exploratory Library, ChemDiv, Inc. Product Library; report dated 30 September 2003; 4 pages.	<input type="checkbox"/>	
	124	SciFinder Report; Piperazine, 1-[2-(3,5-dimethyl-4-nitro-1H-pyrazol-1-yl)-1-oxopropyl]-4-phenyl-; Registry No.: 489449-56-1; Catalogs: Compounds for Screening, Interchim Intermediates; report dated 30 September 2003; 3 pages.	<input type="checkbox"/>	
Examiner Signature				Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A&B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/732,897
				Filing Date	December 9, 2003
				First Named Inventor	Pennell, Andrew M.K.
				Art Unit	1624
				Examiner Name	Emily B. Bernhardt
Sheet	7	of	7	Attorney Docket Number	019934-003720US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	125	SciFinder Report; Piperazine, 1-[(2,4-dinitro-1H-imidazol-1-yl)acetyl]-4-(4-fluorophenyl)-; Registry No.: 313987-12-1; Catalogs: Exploratory Library, Interchim Intermediates, ChemDiv, Inc. Product Library, AsinEx Express Gold Collection, Pharma Library Collection; report dated 30 September 2003; 7 pages.	<input type="checkbox"/>	
	126	SciFinder Report; Piperazine, 1-[(2,4-dinitro-1H-imidazol-1-yl)acetyl]-4-phenyl-; Registry No.: 313987-13-2; Catalogs: Exploratory Library, Interchim Intermediates, Compounds for Screening, ChemDic, Inc. Product Library, AsinEx Express Gold Collection, Pharma Library Collection; report dated 30 September 2003; 7 pages.		
	127	TRENTHAM, et al., Autoimmunity to type II collagen an experimental model of arthritis, J. Exp Med. (1977) 146(3):857-868		
	128	TOKUDA, et al., Pivotal role of CCR1-positive leukocytes in bleomycin-induced lung fibrosis in mice, J Immunol. (2000) 164(5):2745-51.		
	129	WALSH, D. et al., "Synthesis and antiallergy activity of N-[2-(dimethylamino)ethyl]-4-aryl-1-piperazinecarboxamide derivatives" J. Med. Chem. (1990) 33:2028-2032.		

Examiner Signature		Date Considered	
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